

Docket No.: 5618P2949
Express Mail No.: EL651821001US

UNITED STATES PATENT APPLICATION

FOR

INTRAVENTRICULAR SUBSTANCE DELIVERY CATHETER SYSTEM

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INTRAVENTRICULAR SUBSTANCE DELIVERY CATHETER SYSTEM**FIELD OF THE INVENTION**

This invention relates generally to catheters, and more particularly to catheters used to navigate a vascular system 5 in order to access a desired location within a body.

BACKGROUND

It is increasingly important that a physician or surgeon delivering substances, such as drugs, is able to 10 efficiently and accurately locate the desired target tissue for effective delivery of the substance. This is particularly true when the concentration of the substance required at the target site cannot be safely or effectively achieved by introduction of the substance to a location 15 remote from the target site. Moreover, the physician may only want to treat the diseased portion of an organ or tissue and avoid treating the healthy portions.

Such localized treatment is necessary not only for substance delivery but also for other treatments, including 20 myocardial revascularization. Myocardial revascularization is a procedure in which "holes" are formed in ischemic ventricular tissue in order to increase blood flow to the treated area. It is thought that the tissue damage (e.g., holes) encourages growth of blood vessels in the treated area. Similar to substance delivery, myocardial 25 revascularization is a procedure that is preferably performed only on specific areas that require treatment.

One common target site is the left ventricle of the human heart. The left ventricle is particularly important since the left ventricle supplies blood to the entire body 30 with the exception of the lungs. Thus, if the left

ventricle is compromised, a patient will become very ill and may possibly die. The severity of the diseases of the left ventricle coupled with the importance of localized diagnosis and treatment within the left ventricle render the ability 5 to effectively and accurately access specific portions of the left ventricle extremely important.

SUMMARY

The various embodiments described herein use a deflectable guide catheter in conjunction with a needle 10 catheter to access the vascular system, including the heart, of a patient. The guide catheter has a deflecting tip section with a minimized radius of curvature to maximize the area that can be accessed by the device. In addition, the construction of the guide catheter provides for maximum 15 torque response when rotating the guide catheter. In some embodiments, the needle catheter includes a mechanism to impart a sudden force on the needle to improve tissue penetration.

DESCRIPTION OF THE DRAWINGS

20 Various embodiments are illustrated by way of example and not by way of limitation in the figures of the accompanying drawings in which like references indicate similar elements. It should be noted that references to "an", "one", or "various" embodiments in this disclosure are 25 not necessarily to the same embodiment, and such references mean at least one.

Figure 1 shows an embodiment with the guide catheter in a deflected position and the needle catheter protruding from the guide catheter.

30 **Figure 2** shows a side view of the handle portion of the embodiment shown in **Figure 1**.

Figure 3 shows a cross-sectional view of the distal end of an embodiment of the needle catheter.

Figure 4 shows an embodiment of the guide catheter that has a second lumen to accommodate a stabilizing member that 5 protrudes from the guide catheter and rests in the apex of the ventricle.

Figure 5 is a flow chart showing a method of operating a substance delivery system that includes a guide catheter and a needle catheter.

10 **Figure 6** shows a cross-sectional view of an embodiment of the proximal portion of a guide catheter.

Figure 7 shows the distal portion of one embodiment of a guide catheter.

DETAILED DESCRIPTION

15 In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the various embodiments. It will be apparent, however, to one skilled in the art that the various embodiments may be practiced 20 without some of these specific details. The following description and the accompanying drawings provide examples for the purposes of illustration only. However, these examples should not be construed in a limiting sense as they are merely intended to provide exemplary embodiments, rather 25 than to provide an exhaustive list of all possible implementations.

Referring now to **Figure 1**, the distal end of an embodiment is shown, which includes guide catheter 10 and needle catheter 20. Although guide catheter 10 may be used 30 throughout the body of a patient, guide catheter 10 is shown in use within the left ventricle of a human heart. For example, guide catheter 10 may be introduced into the body

of a patient through the femoral artery and directed over aortic arch 12, through aorta 14 and aortic valve 16, and into left ventricle 18.

Once inside left ventricle 18, the distal portion of 5 guide catheter 10 may be advanced, retracted, deflected, and/or rotated in order to position needle catheter 20 in a desired location in order to deliver a substance (e.g., injection) or conduct a procedure. If tissue penetration is desired, needle 24 disposed in the distal end of needle 10 catheter 20 is moved to a deployed position as shown in

Figure 1.

Tip electrode 22 disposed on the distal end of needle catheter 20 is used to determine whether contact with the wall of left ventricle 18 has been made, and if so, whether 15 full needle penetration has been made. One way this is accomplished is that when tip electrode 22 contacts live ventricular tissue, there is an amplitude increase in an electrocardiogram ("ECG") produced by an electrocardiograph or monitor (not shown) electrically coupled to tip electrode 20 22 and to reference electrode 11.

Thus, if there is an initial ECG amplitude increase that indicates contact and a subsequent decrease in ECG amplitude upon the extension of needle 24, then contact 25 between tip electrode 22 and the ventricular wall has been lost. Such a loss of contact can mean that needle 24, upon deployment, did not penetrate the ventricular wall and that needle catheter 20 was pushed away from the ventricular wall. Alternatively, a loss of contact can mean that only partial needle penetration was achieved.

30 Tip electrode 22 can also be used to diagnose the ventricular tissue. For example, in one embodiment, healthy ventricular tissue typically results in a high amplitude ECG when contacted by tip electrode 22. Stunned (e.g.,

ischemic) ventricular tissue and ventricular wall tissue with a reduced thickness are considered to be alive but not functioning properly. When either of these types of ventricular tissue are contacted by tip electrode 22, a high 5 amplitude ECG is typically seen. Dead ventricular tissue and scar tissue, on the other hand, typically each yield an unchanged or low amplitude ECG when contacted by tip electrode 22.

When ECG amplitude information is combined with 10 ventricular wall motion information, the stunned ventricular tissue may be differentiated from healthy tissue.

Specifically, healthy tissue will typically exhibit greater and more rapid wall motion than stunned tissue. Wall motion information may be collected prior to the procedure using 15 ultrasonic, magnetic resonance imaging, and/or various X-ray techniques. Wall motion information may also be collected during the procedure by fluoroscopic observation of tip electrode 22 while in contact with the ventricular wall or by incorporation of a location sensor or an accelerometer 20 (not shown).

In various embodiments, a reference electrode could be coupled to the distal portion of guide catheter 10, a distal portion of needle catheter 20, or an outer surface of the body of the patient. However, the embodiment shown in 25 **Figure 1** has reference electrode 11 (also referred to in some embodiments as an anchor element) disposed on a distal portion of guide catheter 10.

Among other items, **Figure 2** shows handle 25, which is used to control guide catheter 10. Handle 25 includes grip 30 30, which is used to control the rotational and longitudinal position of guide catheter 10. Handle 25 also includes deflection control 32, which is used to control the deflection of the distal portion of guide catheter 10. The

rotational movement of guide catheter 10 and the deflection mechanism will be described more fully below.

The embodiment shown in **Figure 2** also includes the proximal portion of an introducer sheath (used to introduce a catheter into the body of a patient) that has adjustable friction valve 26 and flush port 28. Flush port 28 provides a means for flushing the introducer sheath.

Adjustable friction valve 26 advantageously allows the operator to set the friction level exerted on guide catheter 10 at a level appropriate for the circumstances. For instance, if the catheter is in a position that requires no movement, the operator can essentially lock adjustable friction valve 26 to prevent any rotational or longitudinal movement without affecting the ability of the operator to deflect the distal portion of guide catheter 10 or to longitudinally move needle catheter 20. However, the operator can also set adjustable friction valve 26 to a friction point where guide catheter 10 is movable only by a sufficient amount of force applied to guide catheter 10 by the operator. One example of an adjustable friction valve is a hemostasis valve commercially available from Advanced Cardiovascular Systems, Inc. under the name COPILOT.

The construction of guide catheter 10 provides for accurate positioning of guide catheter 10. For instance, guide catheter 10 comprises handle 25, described above, and a flexible body portion coupled to handle 25. The flexible body portion has dimensions suitable for insertion into and navigation through the body of a patient.

The flexible body portion defines lumen 98 therethrough. In various embodiments, Teflon liner 99 defines lumen 98 (see **Figures 6 and 7**). In use, needle catheter 20 (see **Figure 1**) is disposed within guide catheter lumen 98. It is worth noting here that although the

embodiments disclosed herein focus mainly on guide catheter 10 as a separate entity from needle catheter 20, it is contemplated that the two catheters could be designed and constructed as a single catheter.

5 The flexible body portion of guide catheter 10 includes a distal portion and a proximal portion. The proximal portion, shown in **Figure 6**, comprises flexible element 100 around lumen 98 and outer (e.g., first) braid 102 disposed over flexible element 100. Flexible element 100 is at least 10 one of a coil and a second braid.

If a coil, flexible element 100 is at least one of a single coil and a multi-filar coil (e.g., having multiple coil elements wound together to form a coil). In another embodiment, flexible element 100 is an eight wire braid 15 having 140 picks/inch (a pick is a point where the wires cross when observed along the longitudinal axis of the braid) constructed with flatwire that has a thickness of 0.001 inches and a width of 0.005 inches.

20 Regardless of whether flexible element 100 is a coil or a braid, flexible element 100 prevents compression of the flexible body portion and prevents the collapse of outer braid 102. It is important to reduce the amount of compression experienced by the flexible body portion since 25 lower compression results in more accurate navigation and placement of guide catheter 10 and improved deflection response.

Outer braid 102 disposed over the flexible element 100 is designed to have a maximum torque response, which means that torsional force applied at one end of the flexible body 30 portion will result in an equal rotational movement along the length of the flexible body portion. A maximized torque response is desirable in various embodiments since a low torque response could result in the flexible body portion

acting as a torsional spring, storing rotational force that will eventually be released and cause a "whipping" motion. Such a loss of control is obviously undesirable when attempting to navigate a vascular system and position a 5 guide catheter within the body of a patient.

In one embodiment, outer braid 102 is a sixteen wire braid having 40 picks/inch and is wound at an angle of approximately 55 degrees relative to the longitudinal axis of the flexible body portion. This "lay angle" of 10 approximately 55 degrees has been experimentally determined to yield the maximum torque response for any given wire. During the experimentation, the total torque for a given guide catheter was determined by adding the torques produced by the braid (including torque produced by wires that lay to 15 the right and the left), the liner (e.g., Teflon) beneath the braid, and the plastic coating disposed on the braid (discussed in more detail below).

The proximal portion of the flexible body portion is impregnated with first plastic coating 104 (shown in **Figure 6**). The distal portion of the flexible body portion (having no flexible element or braid) is coated with second plastic coating 112 (see **Figure 7**). In various embodiments, second plastic coating 112 is more flexible than first plastic coating 104 on the proximal portion. The flexibility of 20 both the proximal and distal portions can be varied based on the type and thickness of plastic coating used.

The difference in flexibility between the proximal portion and the distal portion of the flexible body portion advantageously allows for deflection of the distal portion 30 for navigation and positioning of the guide catheter. The distal portion is deflected by tendon wire 106 having a distal end attached to anchor element 11 (**Figure 7**) and a proximal end attached to handle 25 such that manipulation of

deflection control 32 results in deflection of the distal portion of the flexible body portion. Tendon wire 106 can be attached to either the inner diameter or the outer diameter of anchor element 11 in order to impart a 5 deflecting force on anchor element 11.

Tendon wire 106 can be disposed within Teflon sheath 108 located outside of guide catheter lumen 98 but within flexible element 100 and outer braid 102. In one embodiment, tendon wire 106 is a stainless steel wire having 10 a diameter of 0.008 inches.

In various embodiments, tendon wire 106 is coupled to deflection control 32 by a pulley, which gives a mechanical advantage when manipulating deflection control 32 in order to deflect the distal portion of the flexible body portion. 15 Furthermore, tendon wire 106 can be disposed in a straight line along the length of guide catheter 10 or can be spiraled along the length of guide catheter 10.

For instance, the proximal portion may have tendon wire 106 straight or loosely spiraled while the more distal 20 portions of the proximal portion may have a tighter spiral in order to avoid bias towards any one direction. Such a bias can occur around a curve such as the aortic arch. However, a tight spiral can prevent bias and the "whipping" associated with such bias. In addition, spiraling allows 25 certain rotational orientations that would otherwise be difficult or impossible to attain and maintain around a curve.

Anchor element 11 (see **Figures 1 and 7**) is disposed in the distal portion of the flexible body portion and can be 30 at least one of a ring (as shown in **Figure 7**) and an electrode. In various embodiments, anchor element 11 and tendon wire 106 are constructed from electrically conductive material so that the tendon wire/anchor element assembly

serves as part of the deflection mechanism and as a reference electrode, as discussed above. For example, **Figure 2** shows electrical interface 38 coupled to the tendon wire so that an instrument (not shown) can receive an 5 electrical signal from tendon wire 106 to be used as a reference signal to be compared with the electrical signal obtained from tip electrode 22.

In various embodiments, a third plastic coating is disposed on an area just proximal to anchor element 11. The 10 third plastic coating is stiffer than second plastic coating 112 and prevents anchor element 11 from moving proximally due to stresses experienced during deflection. Furthermore, if tendon wire 106 is attached to the outer diameter of anchor element 11, the third plastic coating reduces the 15 peel forces on the bond between tendon wire 106 and anchor element 11 by increasing the radius of curvature (e.g., decreasing the deflection) in the area of the tendon wire/anchor element bond.

In various embodiments, the distal portion of guide 20 catheter 10 has a first piece of elastically deformable material disposed on a first area. In addition, a second piece of elastically deformable material is disposed on a second area of the distal portion of guide catheter 10. The second area being approximately 180 degrees from the first 25 area. Thus, the two pieces of elastically deformable material lay on opposite "sides" of the distal portion of guide catheter 10. The two pieces of elastically deformable material are formed from material having a higher modulus than the plastic coating (e.g., jacket material) that the 30 elastically deformable material displaces.

With the two pieces of elastically deformable material disposed 180 degrees from each other, the tendon wire can be attached at a point 90 degrees from either of the pieces of

elastically deformable material. This configuration and the higher modulus of the elastically deformable material create a deflection bias in the areas of the distal portion of guide catheter 10 that do not have the pieces of elastically deformable material. Thus, the deflection characteristics of the distal portion of guide catheter 10 can be modified based on the elastically deformable material used and the placement of the tendon wire relative to the elastically deformable material.

In other embodiments, a coil of elastically deformable material can be used either in place of or in conjunction with the two pieces of elastically deformable material described above. If used in conjunction with the two pieces of elastically deformable material, the coil can be coupled either to the interior or exterior portions of each of the two pieces of elastically deformable material.

It is worth noting that the elastically deformable material may be attached to the outer portions of guide catheter 10, imbedded or melted into the second plastic coating, attached to a coil or braid structure, and/or contain multiple mounting structures. In general, these "splint" configurations can be used to create a restoring force that generates more stable elastic deformation of the distal portion of guide catheter 10 in a desired direction. The restoring force also facilitates the return of the distal portion of guide catheter 10 to an undeflected state upon release of the tendon wire force. Such a restoring force additionally prevents permanent deformation of the distal portion of guide catheter 10.

Figure 4 shows an example of an embodiment with stabilizing member 88, which is used as a reference point for the flexible body portion when moving guide catheter 78 and needle catheter 82. In embodiments with such a

stabilizing member, the flexible body portion of guide catheter 78 further includes a second lumen and elongate stabilizing member 88 disposed within the second lumen such that the distal end of the stabilizing member protrudes from the distal end of the second lumen. The distal end of stabilizing member 88 can be curved as shown in **Figure 4** or can be curled in the shape of a pig tail in order to prevent injuring tissue.

In use, the distal end of stabilizing member 88 is placed and retained in a location within the body of a patient for reference while needle catheter 82 is used to diagnose and treat surrounding tissue. In **Figure 4**, the apex of the left ventricle serves as the reference point for movement of guide catheter 78 and needle catheter 82. As mentioned above, although the left ventricle is used for illustration, embodiments with stabilizing member 88 could be used in other portions of the body.

Besides use of a stabilizing member, there are other ways to assist an operator in assessing the position of the guide catheter within the body of a patient. For example, a location sensor can be disposed in the distal end of the flexible body portion of the guide catheter. The location sensor could indicate the position of the distal end of the guide catheter by at least one of an electromagnetic mapping system, a radio frequency system, and an ultrasonic mapping system.

Similarly, such a location sensor could be disposed in the distal end of the needle catheter. Moreover, portions of the guide catheter and/or needle catheter can be made of radiopaque material so that the radiopaque portions are detectable with the use of a fluoroscope.

Focusing now on the needle catheter, **Figure 1** shows needle catheter 20 protruding from an opening in guide

catheter 10 with needle 24 in a deployed position into a wall of left ventricle 18. Needle catheter 20 is disposed within the lumen of guide catheter 10 and can be moved longitudinally relative to guide catheter 10 in the embodiment shown. Thus, in use, needle catheter 20 may be inserted along with guide catheter 10 into left ventricle 18 or may be inserted through guide catheter 10 once guide catheter 10 is positioned within left ventricle 18. Alternatively, guide catheter 10 and needle catheter 20 can be constructed as one catheter that is inserted and positioned as a single device.

The construction of needle catheter 20 allows for the transfer of substances through the body of needle catheter 20. Examples of substances that may be delivered include drugs, pharmaceutical agents, fluids, proteins, polypeptides, gene therapy material, cell therapy material, and deoxyribonucleic acid ("DNA").

An embodiment of the distal end of needle catheter 20 of **Figure 1** is shown in **Figure 3**. Specifically, needle catheter 20 includes duplex spring 56 (e.g., two springs wound together, sometimes in opposite directions) impregnated with a polyethylene/ethylene acrylic acid blend. Duplex spring 56 defines a lumen through which substances can be delivered.

In order to give structural support to duplex spring 56, braided shaft 58 is disposed over duplex spring 56. Braided shaft 58 may be double braided and may also have Teflon sheath 59 disposed on the inner diameter of braided shaft 58. Finally, plastic coating 60 is disposed over braided shaft 58. Such a coating advantageously provides a smooth, flexible outer surface for the needle catheter.

Needle 64 is coupled to the inner diameter of duplex spring 56. In various embodiments, needle 64 is coupled to

duplex spring 56 by welding or soldering. An electrical insulator is disposed between needle 64 and electrode 62, discussed below. In the embodiment shown, the electrical insulator is Teflon sheath 76 disposed over at least a portion of needle 64. Similarly, duplex spring 56 has Teflon sheath 77 to electrically insulate duplex spring 56 from electrode 62.

It is worth noting that although Teflon sheath 76 and Teflon sheath 77 are shown as distinct components, sheath 76 and sheath 77 may be constructed as a single sheath, layer, or component. Although Teflon is used herein as an insulator, other suitable insulators could be used. Alternatively, electrically insulative sheath 76 could be omitted so long as needle 64 was constructed out of a non-conductive material such as ceramic.

Electrode 62 (same as tip electrode 22 of **Figure 1**) is disposed on the distal end of the needle catheter. Electrode 62 has an opening through which needle 64 is movable between a retracted position (seen in **Figure 3**) and a deployed position. In the embodiment shown in **Figure 3**, proximal end 70 of electrode 62 functions as a stop to prevent distal movement of needle 64 beyond the deployed position. For instance, once the distal end of duplex spring 56 contacts proximal end 70, needle 64 is in the fully deployed position and cannot move beyond the deployed position.

In various embodiments, electrode 62 has barbs 66 that aid in attachment of electrode 62 to the distal end of the needle catheter. Specifically, electrode 62 is inserted into Teflon sheath 59 until barbs 66 lie within the inner diameter of Teflon sheath 59. Ring 68 is placed over Teflon sheath 59 to tightly mesh Teflon sheath 59 into barbs 66. In various embodiments, ring 68 is welded to electrode 62.

Lead attachment 72 is electrically coupled to electrode 62 in order to obtain an electrical signal from electrode 62. In various embodiments, lead attachment 72 is coupled to lead wire 74, which can be any suitable conductor. In 5 the embodiment shown, lead wire 74 is an insulated molybdenum wire coupled to electrode 62 (e.g., by lead attachment 72), fed out through a hole in braided shaft 58, and wrapped around braided shaft 58 before plastic coating 60 is disposed on braided shaft 58. The insulation on lead 10 wire 74 could be, for example, polyimide, polyester, and/or Teflon.

As shown in **Figure 2**, at the proximal end of the device, lead wire 74 is electrically coupled to electrical interface 44 so that an instrument can receive an electrical 15 signal from electrode 62 through lead wire 74. Adjustable friction valve 34 allows the operator to set the friction level exerted on needle catheter 40 at a desired level. Flush port 36 provides a means for flushing guide catheter 10. Similarly, flush port 42 provides a means for flushing 20 needle catheter 40.

A needle control assembly is coupled to the proximal end of the needle catheter. **Figure 2** shows an embodiment of a needle control assembly. The needle control assembly includes an elastically deformable element coupled to at 25 least one of the duplex spring and the braided shaft of the needle catheter and a release mechanism. The release mechanism releasably engages the elastically deformable element when the elastically deformable element is in a position that corresponds to the needle being in a retracted 30 position.

In the embodiment shown in **Figure 2**, the elastically deformable element is spring 50. The release mechanism includes housing 46 with spring 50 disposed within housing

46. Stop 48 of the release mechanism is disposed within housing 46 and is coupled to the distal end of spring 50 and to at least one of the duplex spring and the braided shaft of the needle catheter.

5 The release mechanism further includes first latch 52 and second latch 54. First latch 52 is pivotally coupled to housing 46 and has a movable portion that is biased towards housing 46 by a spring, or the like. First latch 52 also includes an angled portion and a flat portion that form 10 wedge-shaped protrusion 53 that extends into housing 46 (see **Figure 2**). In operation, when spring 50 is compressed (e.g., moving the needle to the retracted position), stop 48 can move proximally past the angled portion of wedge-shaped protrusion 53.

15 Once past the angled portion, the distal end of stop 48 releasably engages the flat portion of wedge-shaped protrusion 53. Thus, first latch 52 holds spring 50 in a compressed state until released by the operator. In order to ensure that first latch 52 is not inadvertently released, 20 second latch 54 is used to hold first latch 52 in place. Specifically, second latch 54 is pivotally coupled to housing 46 and has a movable portion biased towards housing 46. Second latch 54 releasably engages first latch 52 when the flat portion of first latch 52 is in contact with stop 25 48 in order to prevent first latch 52 from releasing stop 48.

Thus, an operator might retract needle 24 of **Figure 1** by compressing spring 50 of **Figure 2** and "locking" spring 50 in place with first latch 52 and securing first latch 52 30 with second latch 54. After the needle catheter is in a desired penetration location, the operator can release spring 50 with first latch 52 in order to puncture tissue. The "spring-loaded" construction of needle 24 imparts

sufficient force to puncture tissue and maintains sufficient force on needle 24 to hold needle 24 in place once the desired location has been penetrated. Therefore, the release mechanisms disclosed herein advantageously free the 5 operator from having to manually hold needle 24 in a retracted position during catheter positioning and from having to manually hold needle 24 in a deployed position during injection of a substance.

Referring now to **Figure 5**, a flow chart is shown 10 detailing one method of using the embodiments disclosed herein. At block 90, the release mechanism is set to hold the needle in the retracted position. The substance delivery system (e.g., guide catheter and needle catheter) is inserted into the body of a patient at block 92.

15 If the guide catheter and needle catheter are separate devices, one of two methods could be used. First, the guide catheter could be inserted with a guide wire, the guide wire withdrawn, and the needle catheter inserted. Second, the guide catheter and needle catheter could be inserted together (either as a single device or one device disposed 20 within the other, depending on construction).

Next, the substance delivery system is moved to a desired position within the body of the patient at block 94. When the operator is ready to penetrate tissue at block 96, 25 the operator releases the release mechanism in order to puncture tissue at a desired location. At this point the operator will inject a substance into the punctured tissue, if necessary.

It is to be understood that even though numerous 30 characteristics and advantages of various embodiments have been set forth in the foregoing description together with details of structure and function of the various embodiments, this disclosure is illustrative only. Changes

may be made in detail, especially matters of structure and management of parts, without departing from the scope of the various embodiments as expressed by the broad general meaning of the terms of the appended claims.

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